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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,486

04/07/2004

Zhi-Jian Yu

27529

7395

33357 7590 10/28/2008  
ADVANCED MEDICAL OPTICS, INC.  
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EXAMINER

BROWN, COURTNEY A

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,486	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> COURTNEY BROWN	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-25 and 27-57 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 and 47-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-13,21-25,27-46 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/27/2004, 1/10/2005, 12/01/2005, and 11/21/2007</u> .        | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgement of Receipt/Status of Claims***

Receipt of Amendments/Remarks filed on June 24, 2008 is acknowledged. Claims 1, 2, 4-25, 27-57 are pending. Claims 3 and 26 stand cancelled. Claims 1, 2, 5.8, 10, 11, 21, 22, 34, and 55 were amended. Claims 14-20 and 47-54 are withdrawn as being directed to a non-elected invention. Claims 1, 2, 4-13, 21-25, 27-46, and 55-57 are being examined for patentability.

### ***Information Disclosure Statement***

The Information Disclosure Statements (IDS) submitted on August 27, 2004, January 10, 2005, December 1, 2005, and November 21, 2007 have been considered by the examiner.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application

***New Rejection(s) Necessitated by the Amendment filed on June 24, 2008***

***Claim Rejection(s) - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2,4-13, 22-25, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1) and Zhao (US 2003/0228393) further in view of Dykens et al. (S 2003/0105167 A1) and Huth (US 2004/0120916 A1).

***Applicant Claims***

Applicant claims a multipurpose solution and a multi-purpose solution for contact lens care comprising an aqueous liquid medium; 0.1 ppm to about 9.5 ppm

Art Unit: 1616

cetylpyridinium chloride; a second antimicrobial component that is selected from the group consisting of polyhexamethylene biguanide, a polyhexamethylene biguanide salt and polyquaternium-1; a viscosity inducing component selected from the group consisting of cellulose derivatives and mixtures thereof; a buffer component selected from the group consisting of boric acid/sodium hydroxide and boric acid/sodium borate buffers; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant; a chelating component; a tonicity component; and taurine.

***Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)***

Tusè et al. teach an anti-microbial system suitable for formulations in a wide variety of ophthalmic solutions. These compositions are useful for storing, cleaning, or disinfecting a contact lens (abstract) and are stored as aqueous solutions (column 22, 60-end to column 24, lines 50-end). Additionally, Tusè et al. teach the use of antimicrobial preservative components such as cetylpyridinium chloride (CPC) and PHMB (polyhexamethylene biguanide) (column 17, lines 35-41); a viscosity adjusting agent such as cellulose derivatives and hydroxylpropyl methylcellulose (column 18, lines 46-55 and claim 58); a buffer component such as boric acid and sodium borate (column 15, 8-26); a chelating component such as EDTA (claims 10 and 11); and a tonicity component (claim 20).

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims  
(MPEP §2141.012)***

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of potassium chloride as a tonicity agent as opposed to cellulose derivatives. For this reason, the teaching of Dukens et al. is joined. Dykens et al., on page 5, paragraph 48 teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

A final difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane

Art Unit: 1616

protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Araki et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted agents. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè et al. Sodium chloride and potassium chloride are known tonicity agent. Thus, it is obvious to include well-known components in the known composition. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing

Art Unit: 1616

component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980). Thus, combining Tusè with Araki et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1), Zhao (US 2003/0228393), and Huth (US 2004/0120916 A1).

### ***Applicant Claims***

Applicant claims a multi-purpose contact lens disinfecting and cleaning solution comprising an aqueous liquid medium; cetylpyridinium chloride; a second microbial agent; a poly (oxpropylene)-poly (oxyethylene) block copolymer surfactant; and taurine.

### ***Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)***



Art Unit: 1616

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims  
(MPEP §2141.012)***

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Araki et al., Zhao, and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè et al. with the addition of taurine and the other noted components. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as taught by Huth, on page 1, [0002], a contact lens care composition comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè et al.. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980). Thus, combining Tusè with Araki et al., Zhao, and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 34-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849

Art Unit: 1616

A1), and Zhao (US 2003/0228393) further in view of Dykens et al. (S 2003/0105167 A1), and Huth (US 2004/0120916 A1).

### ***Applicant Claims***

Applicant claims a multi-purpose solution for contact lens care comprising an aqueous liquid medium; .1ppm to about 10ppm cetylpyridinium chloride; a non-ionic surfactant; a buffer component comprising boric acid; hydroxypropylmethyl cellulose (the viscosity inducing component); EDTA(a chelating component); a combination of sodium chloride and potassium chloride (the tonicity component); a second antimicrobial component selected from the group consisting of biguanides, biguanide polymers, monomeric and polymeric quaternary ammonium compound, salts and mixtures thereof; and taurine.

### ***Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)***

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

### ***Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)***

Art Unit: 1616

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of potassium chloride as a tonicity agent as opposed to cellulose derivatives. For this reason, the teaching of Dukens et al. is joined. Dykens et al., on page 5, paragraph 48 teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

A final difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè, Araki et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted components. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Together with zinc, taurine is required for proper eye health and vision. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè. Sodium chloride and potassium chloride are known tonicity agents. Thus, it is obvious to include well-known components in the known process. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same

Art Unit: 1616

purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980). Thus, combining Tusè with Araki et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1).

### ***Applicant Claims***

Applicant claims a multi-purpose solution comprising an aqueous liquid medium; about .1 to about 2 ppm cetylpyridinium chloride and a second microbial component selected from the group consisting of polyhexamethylened biguanide (PHMB), a polyhexamethylene buguanide salt and polyquaternium-1.

### ***Determination of the Scope and Content of the Prior Art (MPEP § 2141.01)***

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

### ***Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)***

Art Unit: 1616

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al. and Araki et al. One would have been motivated to make this combination in order to receive the expected benefit of having a multi-purpose solution with an amount of antimicrobial agent that has been taught to be effective in an amount of 1-5000 ppm. Therefore, it would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980).

Art Unit: 1616

Thus, combining Tusè with Araki et al., as claimed in the instant invention, sets forth prima facie obvious subject matter.

### ***Examiner's Response to Applicant's Remarks***

Applicant's arguments with respect to claims 1, 2, 4-13, 21-25, 27-46, and 55-57 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



Art Unit: 1616

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number or the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown  
Patent Examiner

Application/Control Number: 10/820,486

Page 17

Art Unit: 1616

Technology Center 1600

Group Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616